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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
1652	1

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/824,053	Applicant(s) STOUGAARD ET AL.	
	Examiner William W. Moore	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-25,32-41 and 43-82* is/are pending in the application.

4a) Of the above claim(s) *36-41,43,44 and 70-82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-25,32-35 and 45-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse in Paper No. 10 filed October 7, 2002, of Group III, comprising claims 9-25, 32-35, and 45-69, to the extent that the claims describe a polypeptide having hexose oxidase activity, or a substance having hexose oxidase activity, and that comprises at least the hexadecapeptide of SEQ ID NO:3, is acknowledged. The traversal is on the ground(s) that no serious search burden would be required to conduct a search for polypeptides, or substances, that have hexose oxidase activity but comprise some other identifying peptide sequence because any hexose oxidase, or substance having hexose oxidase activity, would be classified in the U.S. classification system in class 435, subclass 190, such as inventions of Groups I, II, and IV-VIII. This is not found persuasive because the independent claim 9, from which claims 10-25 and 32-35 depend, does not require that a polypeptide comprise any other identifying peptide sequence other than that of SEQ ID NO:3, indeed does not require even this peptide sequence in view of the recitation of "and mutiens and variants thereof" in its terminal clause. Applicant's traversal is similarly unpersuasive with respect to joining the elected subject matter of the "substance" of other claims of Group III with, e.g., Groups I, II, and IV-VIII because the independent claim 45, from which claims 46-69 depend, requires that no polypeptide within an indeterminate substance impart hexose oxidase activity to the substance and the only structural characteristic permitting inclusion of claims 45-69 in Group III is the recitation of clause (iii) of the dependent claim 50 of the hexadecapeptide of SEQ ID NO:3. Indeed claims 45-69 do not require even this peptide sequence in a component of a substance in view of the recitation of "and mutiens and variants thereof" in the terminal clause of claim 50. Where the only basis for conducting a search for a specific, claimed, subject matter is the identifying, elected, peptide of SEQ ID NO:3, the classification of the

subject matter is of no assistance, thus the requirement is still deemed proper and is therefore made FINAL. Claims 36-41,43,44 and 70-82 are withdrawn from further consideration and claims 9-25, 32-35, and 45-69 are examined only to the extent that they describe a polypeptide, or a substance comprising a polypeptide, that comprises at least the hexadecapeptide of SEQ ID NO:3 and that has hexose oxidase activity.

Information Disclosure Statement

The information disclosure statement, Paper No. 8, filed November 4, 2002, fails to comply with 37 CFR 1.98(a)(2), because it is incomplete in its provision of documents cited therein. 37 CFR 1.98(a)(2) requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Only certain documents listed were present with Applicant's PTO-Form 1449, specifically, those documents numbered 6-10, 15, 16, 18, 33-35 and 38-43. Three other documents that could not be considered were present as well: two search reports for patent applications and one patent application, or publication, lacking a cover sheet that would have permitted its identification. Paper No. 8 has been placed in the application file, but the information referred to therein has not been considered. The information disclosure statement will be considered upon submission of the listed, but not supplied, documents numbered 1-5, 11-14, 17, 19-32, 36, 37, and 44-94 on Applicant's PTO-Form 1449.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 45-69 are rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility.

A claimed invention must posses a specific, substantial and credible *in vitro* or *in vivo* utility. It is agreed that a polypeptide having hexose oxidase of claims 9-25 and 32-35

not subject to this rejection is disclosed to have utility. Claims 45-69, however, do not require that any polypeptide substance have any enzymatic activity and the specification does not disclose that any substance not a polypeptide is capable of exhibiting hexose oxidase activity. A method of use of a material for further research to determine, e.g., what substances not polypeptides might exhibit an enzymatic activity, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). Applicant is invited to establish a specific utility for an undesignated substance that has, regardless of the presence or absence of any peptide or polypeptide therein, the ability to recognize hexose sugars. It is noted that the specification discloses a polypeptide having hexose oxidase activity comprised within compositions and, had Applicant intended that claims 45-69 describe compositions comprising polypeptides having hexose oxidase activity, amending claims 45-69 to describe such compositions will avoid this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-69 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention, an undefined substance, is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 9-25, 32-35, and 45-69 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to exemplify or describe the preparation of the subject matters of the generic polypeptides, and methods of use thereof, of claims 9-25 and 32-35 and

fails as well to exemplify or describe the preparation of the subject matters of the generic substances, and methods of use thereof, of claims 45-69, which, at best need only comprise a hexadecapeptide. Instead, the specification describes but a single product that meets the functional limitation "having hexose oxidase activity", the hexose oxidase having the amino acid sequence set forth in SEQ ID NO:31. Claims 9-25, 32-35, and 45-69 reach generic polypeptides, or substances, comprising a peptide which, itself, cannot be expected to support the functional limitation. Neither the claims nor the specification describe the design of such generic proteins nor any location therein of the peptide of SEQ ID NO:3 and the specification does not otherwise disclose or suggest the nature or source of any of the generic proteins that meet the limitations of the claims. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. §112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The Court of Appeals for the Federal Circuit held that a claimed invention must be described with such "relevant identifying characteristic[s]" that the public could know that the inventor possessed the invention at the time an application for patent was filed, rather than by a mere "result that one might achieve if one had made that invention". *University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The specification's treatment of the claimed subject matter is considered to be entirely prospective where skilled artisans in the relevant field of molecular biology could not predict the structure, or other properties, of the claimed products and claimed methods of use thereof.

Claims 9-25, 32-35, and 45-69 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a polypeptide having hexose oxidase activity and comprising the amino acid sequence set forth in SEQ ID NO:31,

does not reasonably provide enablement for the preparation or use of a generic polypeptide, or a generic substance, that comprises no more definite structure than a peptide having the sequence of sixteen amino acids of SEQ ID NO:3. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 9-25, 32-35, and 45-69 contemplate an arbitrary assignment of any or all of amino acid substitutions, additions or deletions in a hexose oxidase of any source so long as the a polypeptide, of some substance, comprises somewhere a sequence of sixteen amino acids represented by SEQ ID NO:3. This rejection is stated under the first paragraph of the statute because the specification cannot support the *de novo* design and preparation of generic polypeptides that have hexose oxidase activity and contain somewhere the specific hexadecapeptide having the amino acid sequence set forth in SEQ ID NO:3. Mere sequence perturbation will not enable the design and preparation of nucleotide sequences encoding a myriad of divergent proteases and provide the public with a nucleotide sequence encoding a protease that retains its native function.

It is well settled that 35 U.S.C. §112, first paragraph, requires that a disclosure be sufficiently enabling to allow one of skill in the art to practice the invention as claimed without undue experimentation and that unpredictability in an attempt to practice a claimed invention is a significant factor supporting a rejection under 35 U.S.C. §112, first paragraph, for non-enablement. See, *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (recognizing and applying the "*Forman*" factors). Cf., *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) (citing eight factors relevant to analysis of enablement). The standard set by the CCPA, the precursor of the Court of Appeals for the Federal Circuit, is not to "make and screen" any and all possible alterations because a reasonable correlation must exist between the scope asserted in the claimed subject matter and the scope of guidance the specification provides. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 25 (CCPA 1970) (scope of enablement varies inversely with the degree of unpredictability of factors involved in physiological activity of small peptide hormone); see also, *Ex parte Maizel*, 27 USPQ2d 1662, 1665 (Bd. Pat. App. & Int. 1992)

(functional equivalency of divergent gene products not supported by disclosure only of a single B-cell growth factor allele). The Federal Circuit approved the standard set by the CCPA in *Genentech, Inc. v. Novo-Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997).

The Federal Circuit has also considered whether definitional statements might enable a claim scope argued to extend beyond a disclosed gene product having its native amino acid sequence to embrace a specific variant gene product encoded by a specifically-altered DNA sequence. *Genentech, Inc. v. The Wellcome Found. Ltd.*, 29 F.3d 1555, 31 USPQ2d 1161 (Fed. Cir. 1994). The court held that only a narrow structural and functional definition was enabling precisely because the sweeping definitions of scope in the patent specification could not reasonably have been relied upon by the PTO in issuing the patent. *Genentech*, 29 F.3d 15 at 1564-65, 31 USPQ2d at 1168. Applying the "*Forman*" factors discussed in *Wands, supra*, to Applicant's disclosure, it is apparent that:

a) the specification lacks adequate, specific, guidance for altering the amino acid sequence of SEQ ID NO:31 beyond the peptide region having the amino acid sequence set forth in SEQ ID NO:3 to the extent permitted in the claims,

b) the specification lacks working examples wherein the amino acid sequence of SEQ ID NO:31 is altered to the extent permitted in the claims,

c) in view of the prior art publications of record herein, the state of the art and level of skill in the art do not support such alteration, and,

d) unpredictability exists in the art where no members of the class hexose oxidases have had the majority of the positions in their amino acid sequences specifically identified for concurrent modification.

Thus the present specification cannot be considered to support the scope of the claimed subject even if taken in combination with the teachings available in the prior art. Limitation of the subject matters as indicated in the statement at page 5, lines 24-25, above is required in order to overcome this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-69 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what had been intended by the preamble of claim 45, "[a] substance having hexose oxidase activity", particularly where the substance in the remainder of the claim is a polyacrylamide gel comprising the chaotropic agent, sodium dodecyl sulfate, and a polypeptide wherein presence of the chaotrope must, of necessity, disable any enzymatic activity of any polypeptide in the gel. In view of the fact that a single polypeptide of the further clause of claim 45 is also characterized by two separate bands in the gel – an indication of at least two separate polypeptides – this further limitation cannot constitute a meaningful limitation defining a claimed substance. Claims 46-69 are included in this rejection because they depend from claim 45 but do not otherwise resolve the ambiguities of claim 45. If Applicant had intended to describe compositions comprising a polypeptide that has hexose oxidase activity with claims 45-69, amending these claims to describe (a) composition(s) that comprises a disclosed hexose oxidase with a singular mass characteristic will overcome this rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-65 are rejected under the judicially created doctrine of double patenting over claims 25 and 26 of U. S. Patent No. 6,251,626 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a composition, which may be a substance, which may comprise a disclosed hexose oxidase. Furthermore, there is no apparent reason why applicant was

prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Allowable Subject Matter

Claims 9-25, 32-35 and 45-69 are allowable over the prior art of record which does not disclose or suggest the subject matters of claims 9-25, 32-35 and 50 having a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:3, nor disclose or suggest the subject matters of claims 45-49 and 51-69 wherein a substance having hexose oxidase activity comprises a single polypeptide characterized by separate bands on molecular weight sizing gel and cannot be identified as a hexose oxidase in the presence of a chaotrope.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 7:00AM-5:30PM EST on Mondays and Wednesdays, between 7:00AM-1:30PM EST on Tuesdays and Thursdays, and between 8:30AM and 5:00PM EST on Fridays. **The examiner's direct FAX telephone number is 703.746.3169.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. Further fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
December 20, 2002

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